PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Ting Tina Ye et al.	Confirmation No.:	2367
Serial No.:	09/839,065	Examiner:	M. DeSanto
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Docket No.:	1001.1471101	Customer No.:	28075
For:	MICROCATHETER WITH IMPROVED DISTAL TIP AND TRANSITIONS		

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SUPPLEMENTAL APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Supplemental Appeal Brief. This paper is filed within one month of the March 18, 2008 mailing date of the Notification of Non-Compliant Appeal Brief. It is believed that no fees are due. Permission is hereby granted to charge or credit deposit account number 50-0413 for any errors in fee calculation.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, SciMed Life Systems, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One SciMed Place, Mail Stop A150, Maple Grove, Minnesota 55311-1566. An assignment from the inventors, Ting Tina Ye, Rhoda M. Santos, Elaine Lim, Mai Xuan Tran, Hanh Doan, and Simon Ngoc Huu Nguyen, conveying all right, title and interest in the invention to SciMed Life Systems, Inc. has been recorded at Reel 011729, Frame 0105.

II. RELATED APPEALS AND INTERFERENCES

U.S. Patent Application No. 09/945,225 is a continuation-in-part of the present application and is presently under appeal in light of similar issues and references.

III. STATUS OF CLAIMS

Claims 1 and 41 stand finally rejected under 35 U.S.C. §102(e) as being anticipated by Samson et al., U.S. Patent No. 6,090,099. Claims 1, 3-6, 8-11, 13, 14 and 15 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Samson et al. Claims 1, 3-34, and 41 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Samson et al. in view of Nita et al., U.S. Patent No. 5,951,539. Claim 2 has been cancelled without prejudice, and claims 35-40 have been withdrawn from consideration due to a restriction requirement. Appellants hereby appeal the rejection of claims 1, 3-34 and 41.

IV. STATUS OF AMENDMENTS

A Response After Final and Petition to Withdraw Finality were filed on April 27, 2004 in response to a Final Action mailed on January 28, 2004. After the Appeal Brief was filed on September 28, 2004, an Advisory Action stating that a claim amendment in the Response after Final would not be entered was mailed on November 4, 2004, necessitating this Amended Appeal Brief.

V. SUMMARY OF CLAIMED SUBJECT MATTER[1]

The invention relates to catheters and, more particularly, catheter shafts with improved designs. The inventive catheter has an elongate shaft including a number of layers including an inner liner, a second layer, a third layer, and a fourth layer. The elongate shaft has a proximal end and a distal end. Near the distal end is a distal tip having a shapeable length that may be shaped by thermoforming techniques. The second layer extends from the proximal end of the shaft to a location proximal of the distal end of the shaft. The shapeable length extends for a distance distal of the distal end of the second layer.

Illustrative catheters according to the claims of the present application are shown in Figures 1-4. For example, referring to Figures 1-2, a catheter (10) has a shaft (12). The shaft (12) has a proximal end (14) and a distal end (16). A shapeable length extends near the distal tip (20) of the shaft (12). The shaft (12) has an inner liner (24), a second layer (26) over the inner liner (24), a third layer (30) disposed over the second layer (26), and a fourth layer (44) disposed over the third layer (30). The second layer (26) reaches a distal terminus (28). The region distal of the distal terminus (28) can be shaped using thermoforming techniques.

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[1] The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

Turning now to the claims, claim 1 recites an intravascular catheter (Figure 1, reference number 10) comprising an elongate shaft (Figures 1-3, reference number 12, Figure 4, reference number 212) having a proximal end (Figure 1, reference number 14), a distal end (Figure 1, reference number 16), and a distal tip (Figures 1-4, reference number 20) having a shapeable length that is shapeable by thermoforming techniques (Specification at page 6, lines 10-13, page 9, line 2). The elongate shaft of claim 1 includes an inner liner (Figures 2-4, reference number 24), a second layer (Figures 2 and 4, reference number 26, Figure 3, reference number 126) disposed over the inner liner, the second layer extending from the proximal end of the shaft to a distal terminus (Reference number 28 in Figures 2 and 4, reference number 128 in Figure 3).

The distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length (Specification at page 6, lines 6-13). The elongate shaft also includes a third layer disposed over the second layer (Figures 2-4, reference number 30) and a fourth layer disposed over the third layer (Figures 2-3, reference number 44, Figure 4, reference number 144). The fourth layer includes a proximal end and a distal end, the distal end of the fourth layer extending to the distal end of the shaft (See Figures 2-4).

Claim 3 recites a catheter in accordance with claim 1, wherein the distal terminus is about 4 millimeters from the distal end of the shaft (Specification at page 6, lines 8-10). Claim 4 recites a catheter in accordance with claim 3, wherein the shape of the distal tip can be heat set (Specification at page 6, lines 10-13 and page 9, line 2). Claim 5 recites a catheter in accordance with claim 4, wherein the shape of the distal tip can be heat set by steam (Specification at page 9, line 2).

Claim 6 recites a catheter in accordance with claim 3, wherein the inner liner comprises polytetrafluoroethylene (Specification at page 5, lines 6-7). Claim 7 recites a catheter in

accordance with claim 3, wherein the second layer comprises polyether block amide (Specification at page 6, lines 1-2). Claim 8 recites a catheter in accordance with claim 3, wherein the third layer comprises a coil (Specification at page 6, lines 17-21). Claim 9 recites a catheter in accordance with claim 8, wherein the coil comprises stainless steel (Specification at page 6, lines 17-20). Claim 10 recites a catheter in accordance with claim 8, wherein the coil comprises nickel alloy (Specification at page 6, lines 17-20). Claim 11 recites a catheter in accordance with claim 8, wherein the coil comprises a non-ferrous metal (Specification at page 6, lines 17-21).

Claim 12 recites a catheter in accordance with claim 3, wherein the fourth layer comprises polyether block amide (Specification at page 7, lines 20-21). Claim 13 recites a catheter in accordance with claim 3, wherein the distal end of the shaft has an outside diameter that is less than the outside diameter of the proximal end of the shaft (Specification at page 8, lines 12-13, Figures 2-4, reference number 52). Claim 14 recites a catheter in accordance with claim 3, wherein the distal end of the shaft has a durometer that is less than that of the proximal end of the shaft (Specification at page 8, lines 3-11). Claim 15 recites a catheter in accordance with claim 3, further comprising a radiopaque marker (Specification at page 7, lines 13-19; Figures 2-4, reference number 40). Claim 16 recites a catheter in accordance with claim 15, wherein the distal end of the third layer is secured by the radiopaque marker (Specification at page 7, line 13).

Claim 17 recites a catheter in accordance with claim 3, wherein the second layer further comprises a second segment (Specification at page 9, lines 4-12; Figure 3, reference number 56). Claim 18 recites a catheter in accordance with claim 17, wherein the second segment is disposed

at the inner liner between the distal terminus and the distal end of the shaft (Specification at page 9, lines 4-12).

Independent claim 19 recites an intravascular catheter (Figure 1, reference number 10) comprising an elongate shaft (Figures 1-3, reference number 12, Figure 4, reference number 212) having a proximal end (Figure 1, reference number 14), a distal end (Figure 1, reference number 16), and a distal tip (Figures 1-4, reference number 20) having a shapeable length that is shapeable by thermoforming techniques (Specification at page 6, lines 10-13, page 9, line 2). The elongate shaft of Figure 1 includes an inner liner (Figures 2-4, reference number 24), a second layer disposed over the inner liner (Figures 2 and 4, reference number 26, Figure 3, reference number 126), the second layer extending from the proximal end of the shaft to a distal terminus (Reference number 28 in Figures 2 and 4, reference number 128 in Figure 3). The distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length (Specification at page 6, lines 6-13).

Claim 19 further recites a third layer disposed over the second layer (Figures 2-4, reference number 30); the third layer including a single coil region near the distal end of the shaft and a multiple coil region near the proximal end of the shaft (Specification at page 6, line 22 to page 7, line 5; Figures 2-4 illustrate single coil region 32 and multi-coil region 42). Claim 19 also recites a fourth layer disposed over the third layer (Figures 2-3, reference number 44, Figure 4, reference number 144), the fourth layer including a proximal end and a distal end, wherein the durometer at the proximal end is greater than the durometer at the distal end (Specification at page 8, lines 3-11), the distal end of the fourth layer extending to the distal end of the shaft (Shown in Figures 2-4).

Claim 20 recites a catheter in accordance with claim 19, wherein the distal terminus is about 4 millimeters from the distal end of the shaft (Specification at page 6, lines 8-10). Claim 21 recites a catheter in accordance with claim 20, wherein the shape of the distal tip can be heat set (Specification at page 6, lines 10-13 and page 9, line 2). Claim 22 recites a catheter in accordance with claim 21, wherein the shape of the distal tip can be heat set by steam (Specification at page 9, line 2). Claim 23 recites a catheter in accordance with claim 21, wherein the inner liner comprises polytetrafluoroethylene (Specification at page 5, lines 6-7). Claim 24 recites a catheter in accordance with claim 21, wherein the second layer comprises polyether block amide (Specification at page 6, lines 1-2).

Claim 25 recites a catheter in accordance with claim 21, wherein the third layer comprises a coil (Specification at page 6, lines 17-21). Claim 26 recites a catheter in accordance with claim 25, wherein the coil comprises stainless steel (Specification at page 6, lines 17-20). Claim 27 recites a catheter in accordance with claim 25, wherein the coil comprises nickel alloy (Specification at page 6, lines 17-20). Claim 28 recites a catheter in accordance with claim 25, wherein the coil comprises a non-ferrous metal (Specification at page 6, lines 17-21).

Claim 29 recites a catheter in accordance with claim 21, wherein the fourth layer comprises polyether block amide (Specification at page 7, lines 19-20). Claim 30 recites a catheter in accordance with claim 21, wherein the distal end of the shaft has an outside diameter that is less than the outside diameter of the proximal end of the shaft (Specification at page 8, lines 12-13, Figures 2-4, reference number 52). Claim 31 recites a catheter in accordance with claim 21, further comprising a radiopaque marker (Specification at page 7, lines 13-19; Figures 2-4, reference number 40). Claim 32 recites a catheter in accordance with claim 31, wherein the distal end of the third layer is secured by the radiopaque marker (Specification at page 7, line 13)

Claim 33 recites a catheter in accordance with claim 21, wherein the second layer further comprises a second segment (Specification at page 9, lines 4-12; Figure 3, reference number 56). Claim 34 recites a catheter in accordance with claim 33, wherein the second segment is disposed at the inner liner between the distal terminus and the distal end of the shaft (Specification at page 9, lines 4-12).

Independent claim 41 recites an intravascular catheter (Figures 1-4, reference number 10) comprising an elongate shaft (Figures 1-3, reference number 12, Figure 4, reference number 212) having a proximal end (Figure 1, reference number 14), a distal end (Figure 1, reference number 16), and a distal tip (Figures 1-4, reference number 20) having a shapeable length that is shapeable by thermoforming techniques (Specification at page 6, lines 10-13, page 9, line 2). The elongate shaft of Figure 1 includes an inner liner (Figures 2-4, reference number 24) and a second layer disposed over the inner liner (Figures 2 and 4, reference number 26, Figure 3, reference number 126). Claim 41 further recites that the second layer includes a first segment extending from the proximal end of the shaft to a distal terminus and a second segment extending from the distal terminus to the distal end (Specification at page 9, lines 4-12; Figure 3, reference numbers 54, 56). The distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length (Specification at page 6, lines 6-13).

Also recited in claim 41 is that the elongate shaft includes a third layer disposed over the second layer (Figures 2-4, reference number 30) and a fourth layer disposed over the third layer (Figures 2-3, reference number 44, Figure 4, reference number 144), the fourth layer including a proximal end and a distal end, the distal end of the fourth layer extending to the distal end of the shaft (See Figures 2-4).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1 and 41 are patentable over the §102 rejection relying on Samson et al. (U.S. Patent No. 6,090,099).

B. Whether claims 1, 3-6, 8-11, 13, 14, 15, 17 and 18 are patentable over the §103 rejections relying on Samson et al.

C. Whether claims 1, 3-34 and 41 are patentable over the §103 rejections relying on Samson et al. in view of Nita et al. (U.S. Patent No. 5,951,539).

VII. ARGUMENT

A. Claims 1 and 41 are patentable over the §102 rejection relying on Samson et al. (U.S. Patent No. 6,090,099).

1. *Argument with respect to Claim 1.*

Claim 1 recites:

> 1. An intravascular catheter, comprising:
> an elongate shaft having a proximal end, a distal end, and a distal tip having a shapeable length that is shapeable by thermoforming techniques, the elongate shaft including:
> an inner liner;
> a second layer disposed over the inner liner, the second layer extending from the proximal end of the shaft to a distal terminus; wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length;
> a third layer disposed over the second layer; and
> a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, the distal end of the fourth layer extending to the distal end of the shaft.

The Examiner has asserted that the phrase "a shapeable length that is shapeable by thermoforming techniques" is a product by process claim recitation. However, the characteristic of being shapeable by thermoforming techniques would be understood by one of skill in the art

as not requiring a particular process step in order to become so shapeable. Indeed, the recited element merely indicates that one of skill in the art would understand the recited catheter to be amenable to a further process. This is a recited physical characteristic of the catheter.

As defined in MPEP §2173.05(p)(I), a product by process claim "is a product claim that defines the claimed product in terms of the process by which it is made." The phrase highlighted by the Examiner does not recite a process for making the claimed catheter. As such, the Examiner's refusal to consider the claimed invention in its entirety is improper. In particular, the Examiner has not addressed whether the references cited disclose a catheter that is shapeable by thermoforming techniques.

Appellants submit that the phrase "capable of" is commonly used to further describe structures in product claims, without transforming the product claims into product-by-process claims. The limitation that the tip is "shapable" means that it can be shaped, but is not necessarily shaped. This limitation describes a structural characteristic of the product, not a process step.

A process claim requires the positive recitation of method steps. For example, a process step could recite "shaping the distal tip of the catheter" or "the distal tip shaped by ..." Instead of a positively recited process step, the present claims recite characteristics of the catheter itself. The Examiner appears to be reading the phrase "shapeable by thermoforming techniques" as "shaped by thermoforming techniques," which is clearly an untenable position.

The burden of supporting a rejection under 35 U.S.C. §102 lies with the Examiner. For 35 U.S.C. §102 rejections, the reference must teach every element of the claim, as noted in MPEP §2131. The Examiner has failed to consider at least one claim element in making the present rejection, and there is no valid legal basis for this failure. The Examiner has failed to

identify where in the cited reference at least one claim element is taught. Therefore, the Examiner has not established a *prima facie* case of unpatentability.

In response to the Appellants earlier arguments, instead of focusing on the claim language, the Examiner provided citation to several cases cited in the MPEP. However, none of the cited case law supports the Examiner's interpretation of the claim language. The cited cases are as follows:

In re Hack, 114 USPQ 161 (CCPA 1957), is apparently cited in support of the Examiner's interpretation of "shapeable" as a product-by-process limitation. It appears to Appellants that the citation of *Hack* is due to its appearance at MPEP §2112.02 as it does not otherwise appear to be on point. The case does not involve product-by-process claims or assertions of such claims. *Hack* discusses new uses for old products, stating that patentability of a composition or machine cannot be predicated on a new use, and that only process or method claims can protect a new use. In *Hack*, the product was asserted as being patentable based on an intended use. In the present case, the claims are directed to a product with specific structural features that are not found in the cited prior art. No intended use is claimed or relied on for distinguishing the claimed invention from the prior art.

The Examiner also cites *In re Thorpe, et al.* 227 USPQ 964 (Fed. Cir. 1985). As with *Hack,* it appears to Appellants that *Thorpe et al.* is cited mainly because it appears in MPEP §2113. However, the facts of *Thorpe et al.* are quite different from the instant case. The applicant in *Thorpe et al.* did not assert the product of its process was different from the product of the prior art, and merely argued that because the process was patentable, the resulting product should be, too. The court re-asserted the standard rule that while process claims may be allowable, the product in a product-by-process claim must be allowable based on distinguishing

characteristics. The facts of the instant situation are quite different. In the instant case, Appellants do assert that their product differs structurally from the product of the prior art. Additionally, while the claims at issue in *Thorpe et al.* stated "product of the process of claim 1" and were thus clearly product-by-process claims, the instant claims are product claims.

The Examiner also cites *In re May, et al.* 197 USPQ 601 (CCPA, 1978). Again, *May et al.* appears to be cited primarily because it is cited in MPEP §2112.02. However, the facts of *May et al.* are also quite different from the instant case. In *May et al.*, the applicant claimed a new use for a known drug product. The issues related to whether the effect of the drug was unexpected, not to any structural differences in products or assertions of product-by-process claims.

The recited claim element of a "shapeable length that is shapeable by thermoforming techniques" has been expressly ignored by the Examiner in contradiction to the requirements of MPEP §2131. The phrase clearly does not recite how the catheter was formed, and is not a product by process recitation. Therefore, a *prima facie* position has not been established. Appellants do not believe that Samson et al. disclose a shapeable length that is shapeable by thermoforming techniques, and the Examiner has not even asserted such a disclosure. In light thereof, Appellants request the rejection of claim 1 be reversed.

2. *Argument with respect to Claim 41.*

Claim 41 also recites a distal tip having a shapeable length that is shapeable by thermoforming techniques. Therefore, claim 41 is subject to analysis similar to the above for claim 1, and a *prima facie* case of unpatentability has not been established.

In light of the above remarks, Appellants also request that the rejection of claim 41 be reversed.

B. Claims 1, 3-6, 8-11, 13-15, 17 and 18 are patentable over the §103 rejections relying on Samson et al.

1. *Argument with respect to claims 1, 3, 6, 8-11, 13-15, 17 and 18.*

As described above, claim 1 recites a catheter including a shapeable length that is shapeable by thermoforming techniques, and that recited element is not disclosed by Samson et al. Appellants cannot find, and the Examiner has not cited, any part of the Samson et al. reference disclosing or fairly suggesting a catheter portion amenable to shaping by thermoforming techniques. Further, because the Examiner has incorrectly interpreted a device claim limitation as a product-by-process recitation, the Examiner has failed to establish a *prima facie* case of unpatentability. In light thereof, claim 1, as well as dependent claims 3-6, 8-11, 13-15, 17 and 18, are all believed to be patentable over Samson et al. under §103.

2. *Argument with respect to claims 4-5.*

Claim 4 depends from claim 1 and further recites that the shape of the distal tip can be heat set, while claim 5 depends from claim 4 and recites that the shape of the distal tip can be heat set by steam. Again, the language of each of claims 4-5 recites "can be", indicating a structural characteristic of the distal tip of the catheter, rather than reciting a process step for making the catheter shaft. Even if the noted "shapeable by thermoforming techniques" language from claim 1 is considered a product by process recitation (an interpretation with which Appellants strongly disagree), the language of claims 4 and 5 even more clearly states the material characteristic that not only can the material be thermoformed, it is also subject to being heat set and heat set by steam. Because the Samson et al. reference contains no reference to shapeability, heat setting, and heat setting by steam, claims 4 and 5 are believed further patentable over Samson et al. The Examiner has again failed to consider the claim recitations in

contradiction to the instructions of MPEP §2131. Therefore, a *prima facie* case of unpatentability has not been stated, and, as explained above, it is believed that claims 4 and 5 are patentable over Samson et al. As such, the rejections of claims 4 and 5 should be overturned.

C. Claims 1, 3-34 and 41 are patentable over the §103 rejections relying on Samson et al. in view of Nita et al. (U.S. Patent No. 5,951,539).

1. *Argument with respect to claims 1, 3, 6-20, and 23-34.*

Claims 1 and 19 both recite an elongate shaft having a distal tip having a shapeable length that is shapeable by thermoforming techniques. Appellants note that the claim recitation that the catheter includes "a shapeable length that is shapeable by thermoforming techniques" has been incorrectly interpreted as creating a product-by-process limitation that. Again, there is no process of making the catheter recited. With respect to claims 1, 3 and 6-18, therefore, a *prima facie* case of unpatentability has not been established. Claim 19 likewise recites a catheter having a shapeable length that is shapeable by thermoforming techniques. Therefore, like reasoning applies to claim 19, and no *prima facie* case of unpatentability has been stated for any of claims 19, 20 and 23-34.

While the above is believed to be sufficient basis for overturning the standing rejections, Appellants further note that Nita et al. do not fairly suggest a shapeable length shapeable by thermoforming techniques, either. In particular, while Figures 14A-14G illustrate a number of steps taken during catheter formation to modify the cross-sectional (longitudinal or axial) features of the Nita et al. catheter, Appellants do not believe that one of skill in the art would consider changes in the cross-sectional characteristics of a catheter shaft as creating a shapeable catheter. Indeed, these Figures merely show the construction of the catheter as a number of

pieces for a catheter are joined together. One of skill in the art would understand that a shapeable length indicates that the shape which is given is defined along the axial length of the catheter and may include, for example, a modification of cant, or inducement of curvature.

2. *Argument with respect to claims 4, 5, 21 and 22.*

The above arguments with respect to base claims 1 and 19 apply as well to claims 4, 5, 21, and 22. Additional comments for these dependent claims provide further support for reversal of the standing rejections.

Claims 4 and 21 further recite that the shape of the distal tip can be heat set, while claims 5 and 22 recite that the shape of the distal tip can be heat set by steam. Even if the phrase "shapeable by thermoforming techniques" of the base independent claims 1 and 19 is interpreted as a product-by-process limitation (an interpretation Appellants traverse), the recitations of each of claims 4, 5, 21 and 22 are clearly material properties for the shapeable distal tip. As the Examiner has failed to identify where in either reference such properties are disclosed or suggested, a *prima facie* case of unpatentability for claims 4, 5, 21, and 22 has not been established. Appellants have not noted such disclosure in either reference. Therefore, Appellants request that the rejections of these claims be reversed.

3. *Argument with respect to claim 41.*

With respect to claim 41, Appellants note that the claim recitation that the catheter includes "a shapeable length that is shapeable by thermoforming techniques" has been incorrectly interpreted as creating a product-by-process limitation. Again, there is no process of making the catheter recited. With respect to claim 41, therefore, a *prima facie* case of unpatentability has not been established.

While the above is believed to be sufficient basis for overturning the standing rejections, Appellants further note that Nita et al. do not fairly suggest a shapeable length shapeable by thermoforming techniques, either. In particular, while Figures 14A-14G illustrate a number of steps taken during catheter formation to modify the cross-sectional (longitudinal or axial) features of the Nita et al. catheter, Appellants do not believe that one of skill in the art would consider changes in the cross-sectional characteristics of a catheter shaft as creating a shapeable catheter. Indeed, these Figures merely show the construction of the catheter as a number of pieces for a catheter are joined together. One of skill in the art would understand that a shapeable length indicates that the shape which is given is defined along the axial length of the catheter and may include, for example, a modification of cant, or inducement of curvature.

In light of the above remarks, Appellants also request that the rejection of claim 41 be reversed.

D. The Examiner's Comment.

In paragraph 7 of the Final Office Action, the Examiner asserts:

> The examiner still believes that the catheter of Sampson will perform the same function of the applicant's claimed invention (wherein Sampson's catheter will be able to be shaped) and thus still read on the applicant's invention.

Appellants are confused by this conclusory statement, which appears to assert that the recited physical characteristics of the catheter's shapeable distal tip are "function" recitations, which is clearly not the case. Further, if this statement is a basis for any of the §102(e) or 103(a) rejections specified by the Examiner, Appellants are unable to ascertain with any specificity how the Examiner has arrived at such a belief. Appellants feel it necessary to address this comment as it is unclear whether the Examiner's personal belief or knowledge has provided a basis for the

noted rejections. If so, then Appellants feel it is necessary under MPEP §2144.03 to request citation of a reference supporting the Examiner's knowledge or belief, so as to avoid allowing the opportunity to contest the statement to lapse. Appellants request that, if this statement does provide a basis for any rejection, a fuller explanation of the underlying reasoning and a citation to references be provided.

E. Conclusion

For the reasons stated above, the rejections of claims 1, 3-34, and 41 under 35 U.S.C. §§102(e), and 103(a) should be reversed.

Respectfully submitted,

Ting Tina Ye, et al.

By their attorney,

Date: 4/9/08

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VIII. CLAIMS APPENDIX

1. An intravascular catheter, comprising:

an elongate shaft having a proximal end, a distal end, and a distal tip having a shapeable length that is shapeable by thermoforming techniques, the elongate shaft including:

an inner liner;

a second layer disposed over the inner liner, the second layer extending from the proximal end of the shaft to a distal terminus; wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length;

a third layer disposed over the second layer; and

a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, the distal end of the fourth layer extending to the distal end of the shaft.

3. The catheter in accordance with claim 1, wherein the distal terminus is about 4 millimeters from the distal end of the shaft.

4. The catheter in accordance with claim 3, wherein the shape of the distal tip can be heat set.

5. The catheter in accordance with claim 4, wherein the shape of the distal tip can be heat set by steam.

6. The catheter in accordance with claim 3, wherein the inner liner comprises polytetrafluoroethylene.

7. The catheter in accordance with claim 3, wherein the second layer comprises polyether block amide.

8. The catheter in accordance with claim 3, wherein the third layer comprises a coil.

9. The catheter in accordance with claim 8, wherein the coil comprises stainless steel.

10. The catheter in accordance with claim 8, wherein the coil comprises nickel alloy.

11. The catheter in accordance with claim 8, wherein the coil comprises a non-ferrous metal.

12. The catheter in accordance with claim 3, wherein the fourth layer comprises polyether block amide.

13. The catheter in accordance with claim 3, wherein the distal end of the shaft has an outside diameter that is less than the outside diameter of the proximal end of the shaft.

14. The catheter in accordance with claim 3, wherein the distal end of the shaft has a durometer that is less than that of the proximal end of the shaft.

15. The catheter in accordance with claim 3, further comprising a radiopaque marker.

16. The catheter in accordance with claim 15, wherein the distal end of the third layer is secured by the radiopaque marker.

17. The catheter in accordance with claim 3, wherein the second layer further comprises a second segment.

18. The catheter in accordance with claim 17, wherein the second segment is disposed at the inner liner between the distal terminus and the distal end of the shaft.

19. An intravascular catheter, comprising:

an elongate shaft having a proximal end, a distal end, and a distal tip having a shapeable length that is shapeable by thermoforming techniques, the elongate shaft including:

an inner liner;

a second layer disposed over the inner liner, the second layer extending from the proximal end of the shaft to a distal terminus, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length;

a third layer disposed over the second layer; the third layer including a single coil region near the distal end of the shaft and a multiple coil region near the proximal end of the shaft; and

a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, wherein the durometer at the proximal end is greater than the durometer at the distal end, the distal end of the fourth layer extending to the distal end of the shaft.

20. The catheter in accordance with claim 19, wherein the distal terminus is about 4 millimeters from the distal end of the shaft.

21. The catheter in accordance with claim 20, wherein the shape of the distal tip can be heat set.

22. The catheter in accordance with claim 21, wherein the shape of the distal tip can be heat set by steam.

23. The catheter in accordance with claim 21, wherein the inner liner comprises polytetrafluoroethylene.

24. The catheter in accordance with claim 21, wherein the second layer comprises polyether block amide.

25. The catheter in accordance with claim 21, wherein the third layer comprises a coil.

26. The catheter in accordance with claim 25, wherein the coil comprises stainless steel.

27. The catheter in accordance with claim 25, wherein the coil comprises nickel alloy.

28. The catheter in accordance with claim 25, wherein the third layer comprises a non-ferrous metal.

29. The catheter in accordance with claim 21, wherein the fourth layer comprises polyether block amide.

30. The catheter in accordance with claim 21, wherein the distal end of the shaft has an outside diameter that is less than the outside diameter of the proximal end of the shaft.

31. The catheter in accordance with claim 21, further comprising a radiopaque marker.

32. The catheter in accordance with claim 31, wherein a distal end of the third layer is secured by the radiopaque marker.

33. The catheter in accordance with claim 21, wherein the second layer further comprises a second segment.

34. The catheter in accordance with claim 33, wherein the second segment is disposed at the inner liner between the distal terminus and the distal end of the shaft.

41. An intravascular catheter, comprising:

an elongate shaft having a proximal end, a distal end, and a distal tip having a shapeable length that is shapeable by thermoforming techniques, the elongate shaft including:

an inner liner;

a second layer disposed over the inner liner, the second layer including a first segment extending from the proximal end of the shaft to a distal terminus and a second segment extending from the distal terminus to the proximal end; wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length;

a third layer disposed over the second layer; and

a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, the distal end of the fourth layer extending to the distal end of the shaft.

X. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

The related proceedings in U.S. Patent Application No. 09/945,225 are presently under appeal subject to the same timeline as the present appeal. Therefore there are no decisions to cite or provide copies of at this time.